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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/772,790

Applicant(s)

SCHERSL, ENDRE MARKOVITS

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2003 and 21 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 36-61 is/are pending in the application.
- 4a) Of the above claim(s) 37-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Acknowledgment is made of applicant's claim for foreign priority to Chile 209-2000 under 35 U.S.C. 119(a)-(d). The certified copy has been filed in the instant Application on November 5, 2002 in Paper No. 7.

Applicant's preliminary amendment in response to the Restriction Requirement (July 16, 2002) filed January 21, 2003 in Paper No. 9 is acknowledged, wherein claims 12-35 have been cancelled and claims 1-11 are amended, and claims 36-61 are newly submitted.

Applicant's supplemental preliminary amendment in response to the Restriction Requirement (July 16, 2002) and Notice of Non-Responsive Amendment (April 9, 2003), submitted May 13, 2003 in Paper No. 11 is acknowledged, wherein claims 6-35 are cancelled and claims 1-5 have been amended, and claim 36 is newly submitted. However, it is noted that claim 36 in the amendment Paper No. 11 is same as claim 36 added in the amendment Paper No. 9.

Currently, claims 1-5 and 36-61 are pending in this application.

Election/Restrictions

Applicant's election with traverse of the invention of Group I, claims 1-5, and the species of esters of policosanols, submitted May 13, 2003 in Paper No. 11 is acknowledged.

It is noted that esters of policosanols are considered to be a genus, not a single specified specie of an individual active compound. Nonetheless, on consideration by the

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examiner, the specie election requirement is modified to include all esters of policosanols and carboxylic acids recited in claims 1-5 and 36 as a single specie, elected by Applicant in Paper No.11.

The traversal is on the ground(s) that inventions of Group I and II do not show a distinct and separate. This is not found persuasive. As discussed in the "Restriction Requirement" in the previous Office Action mailed July 16, 2002 (see page 3), Group I drawn to a composition and Group II drawn to a method for lowering LDL-cholesterol levels or for elevating HDL-cholesterol levels in blood of a mammal comprising the composition are seen to be separate and distinct inventions since they are related as product and process of use. As discussed in the Restriction Requirement at page 3, the criteria for distinct inventions: (1) the process for using the product as claimed can be practiced with another materially different product (MPEP § 806.05(h)). In the instant case, for example, a statin (e.g., simvastatin) may be used in a method for lowering LDL-cholesterol levels and triglycerides or for elevating HDL-cholesterol levels in blood of a mammal". Thus, the composition containing a statin (e.g., simvastatin) is another materially different product -- which is materially different from the product as claimed, an ester of policosanol, and this statin composition, can be used in the claimed method herein for lowering LDL-cholesterol levels and triglycerides or for elevating HDL-cholesterol levels in blood of a mammal.

Moreover, the search field for a composition is non-coextensive with the search field for a method of treating a patient employing the same composition. A reference to

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the composition herein would not necessarily be a reference to the method of treatment under 35 USC 103.

Therefore, the requirement is still deemed proper and is made FINAL.

Claims 37-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-5 and 36 will be examined on the merits herein.

Abstract

The abstract of the disclosure is objected to because the instant abstract contains more than a single paragraph and exceeds 250 words. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details (emphasis added).

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Levin et al. (US 3,031,376, PTO-1449 submitted January 2, 2002).

Levin et al. discloses a composition comprising one or more esters of tetracosanol, hexacosanol, octacosanol, and triacontanol, wherein the acid moiety of esters is a carboxylic acid containing from 2 to 22 carbon such as acetic acid (having 2 carbons) and propionic acid (having 3 carbons), (see particularly col.1 lines 13-17; col.3 lines 49-53 and 60-71; Example 3 at col.7 lines 19-26). Levin et al. also discloses that the composition therein further comprises food as a carrier such as vegetable oils as a liquid carrier (see particularly col. 4 lines 10-12 and 34-38). Levin et al. also discloses that the composition therein further comprises corn starch and/or lactose (known excipients) and/or vitamins (known antioxidants) (see particularly col. 4 lines 19 and 22). Levin et al. further discloses that the composition herein to be administered to human mammals and animals is for reducing anoxia, improving physical endurance, reducing fatigue, and stimulating or improving heart response (see col.3 lines 53-57).

Thus, Levin et al. anticipates claims 1-5.

Applicant is requested to note that it is well settled that "intended use" of a composition or product, e.g., "lowering LDL-cholesterol levels or elevating HDL-cholesterol levels in blood of a mammal", will not further limit claims drawn to a

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composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (US 3,031,376, PTO-1449 submitted January 2, 2002) in view of Granja et al. (US 5,663,156, PTO-892) and Hasegawa et al. (PTO-982, the English abstract) further in view of Bundgaard (Book, "Design of prodrugs" Chapter 1, page 1).

The same disclosure of Levin et al. has been discussed above (see supra page 4-5).

Levin et al. does not expressly disclose that the acid moiety of esters, a carboxylic acid, is linoleic acid or other particular fatty acids herein.

Granja et al. discloses that the instant preferred policosanols such as tetracosanol, hexacosanol, heptacosanol, octacosanol, and triacontanol are useful in compositions and methods for treating hypercholesterolemia and atherosclerosis (see abstract, Table 1-2 at col.3, Example 11-13 at col.12-14 and claims 1-20).

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Hasegawa et al. discloses that the instant preferred fatty acid, linoleic acid, is known to have hypocholesteremic effect and lower the serum cholesterol levels, and therefore is useful in compositions (e.g., sunflower oil or vegetable oils known containing linoleic acid) for treating hypercholesterolemia (see the English Abstract).

Bundgaard teaches that esters of actives are most common prodrugs since esters of actives containing hydroxyl and carboxyl groups (also known as hydroxyl group in an alcohol and carboxyl group in a carboxylic acid conjugated or esterified by an ester bond) are hydrolyzed within the body (in vivo) by cleaving the ester bond to regenerate the active drug substances (see the bottom paragraph at page 1).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular carboxylic acid such as the instant preferred fatty acid, linoleic acid, as acid moiety of esters of tetracosanol, hexacosanol, octacosanol, and triacontanol in the claimed composition herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular carboxylic acid such as the instant preferred fatty acid, linoleic acid, as the acid moiety of esters of the policosanol herein such as tetracosanol, hexacosanol, octacosanol, and triacontanol in the claimed composition herein, since esters of tetracosanol, hexacosanol, octacosanol, and triacontanol having the acid moiety such as acetic acid and propionic acid are known to be useful in compositions to be administered for therapeutic purposes (e.g., stimulating or improving heart response) according to Levin et al. Moreover, the instant preferred policosanol such as tetracosanol, hexacosanol, octacosanol, or triacontanol is known to

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be useful in compositions for treating hypercholesterolemia according to Granja et al. A fatty acid such as the instant preferred fatty acid, linoleic acid, alone is also known to be useful in compositions for treating hypercholesterolemia according to Hasegawa et al.

Further, the esters herein having two moieties, the preferred policosanol and linoleic acid, would be hydrolyzed within the body (in vivo) by cleaving the ester bond to regenerate two active drugs, the policosanol and linoleic acid, in the body, based on the well known teachings of esters as prodrugs in pharmaceutical art according to Bundgaard.

Therefore, one of ordinary skill in the art would have reasonably expected that conjugating the policosanol such as tetracosanol, hexacosanol, octacosanol, or triacontanol with a fatty acid such as linoleic acid, into an ester in a composition to be administered, and the ester regenerating the policosanol and linoleic acid in the body after administration, both known useful for the same purpose, i.e., treating hypercholesterolemia, would improve the therapeutic effects for treating the same disorder, hypercholesterolemia, and/or would produce additive therapeutic effects in treating the same. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) regarding combination inventions. It is considered prima facie obvious to combine two active composition components into a single composition to form a third composition useful for the very same purpose.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

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In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
June 11, 2003